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The Regulation of Genetically Engineered Animals: Going From Bad to Worse

Genetically engineered animals raise a number of issues that might potentially call for regulation. Animals may pose human health risks if used as food, environmental risks if they escape from confinement, or animal health or food quality issues where they are genetically adapted to produce valuable drugs.

Since genetic engineering is capable of producing so many different kinds of animals for so many purposes, a thorough analysis of the adequacy of current regulation is well beyond the scope of this paper. Here I will confine myself to environmental risks and summarize the current regulatory climate. What I have to say is genuinely discouraging. Not only are animals not being adequately regulated now, but, under the Bush Administration, there is little chance that they ever will be.

GENETICALLY ENGINEERED ANIMALS! ANYTHING BUT NATURAL

We must begin with the basic point. Genetic engineering is a radically new technology, and anything but natural. Modern gene transfer technologies permit artificial gene transfers across species, family and even kingdom lines. Genes from cows can be put in fish; genes from butterflies into tomatoes; genes from moths into potatoes. With genetic engineering the number of potential new combinations is almost limitless. While we now have considerable experience with genetically engineered organisms, most of it involves microorganisms used under laboratory conditions. We have much less experience with environmental release of engineered organisms. In the case of released animals, we have almost no experience.

While the process of genetic engineering is not inherently dangerous and should not by itself lead to prohibitions, it does have the potential to modify organisms' traits and behavior in ways that are not well understood and not easy to predict. Particularly where the animals will be released—accidentally or deliberately—into the environment, the process of engineering creates sufficient uncertainty that it warrants a red flag of caution.

ENVIRONMENTAL RISKS

Organisms with new combinations of genes can exhibit new combinations of traits, and new combinations of traits may enable new behaviors in the environment. How organisms with new traits will fare in the environment is difficult to predict. The factors influencing success and competition are many and complex. But new trait combinations have the potential to improve an organism's chances of success in the environment. If this happens, an organism can displace existing organisms or otherwise disturb existing ecosystems.

Consider fish. In contrast to some domesticated animals such as cows or sheep, which are unlikely to survive in the wild without human assistance, fish are wild animals well adapted to their environment. Even small modifications by genetic engineering could equip them to survive in a broader range of habitats.

A good example of a one gene change that could have dramatic impact on fish survival involves the so-called "antifreeze" gene. Such genes, available from flounder, code for proteins which can keep fish blood from freezing in arctic waters. So far, antifreeze genes have been transferred into several warm-water fish, including carp. With the antifreeze protein in their blood, the warm-water carp can survive in cold waters where they might displace native cold-water fish or in other ways disturb the aquatic ecosystem.

Another example involves genes for growth hormones. Auburn University scientists have recently transferred growth hormones from other fish and mammals into carp and catfish. Like cold tolerance, fast growth can enable a fish to displace other species and disrupt food chains. In both cases, the new gene can move into any fish that can breed with the engineered fish.

Generally, the same concerns apply to the release of any genetically engineered animal into the environment. Whether an insect, a snail, a mouse or a cat, animals with modified growth rates or temperature tolerances or a multitude of other new traits pose the risk of disrupting ecosystems in harmful ways. Since genetic engineering has the ability ultimately to transfer an unlimited number of new traits into animals, its risks are likely to be greater than those posed by traditional breeding.

Moreover, in addition to the desired modifications, some gene transfers may have effects the genetic engineers did not want, and could not predict. A sad illustration is afforded by the so-called Beltsville pig. In this case, researchers at U.S. Department of Agriculture's (USDA) Beltsville laboratory succeeded in transferring human growth hormone genes to pigs in hopes of producing leaner meat. Instead, the pigs have proven to be crippled, cross-eyed and immune-compromised. Other, less obvious, secondary effects may occur with other gene transfers. Some of these may affect behavior and impact on release.

Finally, as shown by the unexpected effect of chloroflourocarbons (CFCs) on the earth's atmosphere, our ability to predict the impacts of technology is limited. It is possible that genetic engineering, too, may pose novel risks that we have yet to appreciate.

THE FEDERAL BIOTECHNOLOGY REGULATORY FRAMEWORK

The American Fisheries Society (AFS) has recently issued a position statement highlighting the risks of the release of genetically engineered fish and concluding that such releases ought to be overseen by government (Kapuchinski and Hallerman, 1990).

Unfortunately, the American Fisheries Society also noted that the Federal Coordinated Framework does not require the necessary oversight.[1] And the Fisheries Society is correct. No comprehensive federal authority exists under which the releases of fish will be reviewed. In fact, little authority exists to control the environmental impacts of any genetically engineered animals—be they fish, fowl or insect. *Right now, anyone who wished to genetically engineer and release a frog—or for that matter, mink, dog or rat—into the environment is generally free to do so without fear of federal repercussions.*

This information may surprise some readers who perhaps believe that the federal government has a comprehensive framework in place. In fact, the framework that does exist ignored, from its inception, the environmental impacts of animals. I will say a few words about its inadequacies below, but unfortunately, the framework is rapidly becoming a moot point. The Bush Administration engaged in an effort not simply to stall or weaken implementation of the framework, but to dismantle it entirely.

APPLICABILITY TO ANIMALS

Before I turn to the 1992 efforts of the Bush Administration, let me briefly touch on the history and components of the federal framework and its relevance to the control of environmental risks posed by animals.

In 1983, the Reagan Administration orchestrated a multiagency effort to develop a policy to regulate biotechnology and its products. Operating out of the Office of Science and Technology Policy, Administration officials gathered together representatives of USDA, the Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and other agencies to evaluate the statutes they administered for their applicability to biotechnology. In 1984 and 1986, the Agencies published statements outlining how their statutes would be applied to products expected from the new technology. Those statements constitute the core of Federal Framework for biotechnology regulation.

Perhaps because so few engineered animals were under development in the 1980s, the Framework said little about the environmental risks posed by animals.[1] [2] Although a few of the statutes that make up the framework could potentially be applied to releases of animals, no attempt has been made to do so.

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[1] USDA officials have indicated that, instead of FIFRA, they intend to use the weaker authority of the Plant Pest Act to regulate genetically engineered pest control agents. See Payne, 1992.

[2] Almost all the discussion of animals related to the health effects of genetically altered animals used as food.

One of these statutes, the Plant Pest Act, for example, could apply to animals that meet its definition as plants pests. Release of such organisms, which might include genetically engineered insects, slugs or nematodes, could be covered by the existing Plant Pest Act program. The statutory definition of a plant pest, however, is severely restricted—covering only invertebrates. Vertebrate animals, like fish or frogs, are completely excluded from the coverage of the statute.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is another statute under which animals could potentially be regulated. Insects that prey on pest organisms, for example, are considered pesticides under FIFRA. Engineered animals developed for this purpose would be subject to regulation as pesticides under FIFRA. Currently, however, EPA exempts invertebrate animal pesticides from regulation under FIFRA on the grounds that such animals are adequately overseen by the USDA. USDA, in turn, has made little effort to implement its authorities to regulate animals (Payne, 1992).

It should be also noted that EPA's interpretation of the jurisdiction of the Toxic Substances Control Act (TSCA) is broad enough to cover all living organisms, including animals, but that as a matter of policy the Agency has restricted its TSCA program to microorganisms.

Finally, the National Institutes of Health (NIH) Guidelines require NIH approval for the release of genetically engineered animals used in research. The guidelines, however, cover only government-funded research. Private enterprises, for example, commercial fish farms or pet breeders, are not covered by the guidelines.

In summary, except for animals used in federally funded research, developed for pest control or invertebrate animals classified as plant pests, the release of genetically engineered animals is not, and does not have the potential of being, regulated under the Federal Framework for the Regulation of Biotechnology. *From anemones to zebras, most animals can be engineered by anyone, for any purpose, and released at will.*

THE COUNCIL ON COMPETITIVENESS

In retrospect, the evolution of the current (1992) biotechnology policy has been a steady downhill slide. The Biotechnology Regulatory Framework developed by the Reagan Administration promised at least four new rules or guidelines: two implementing USDA authorities[3] and two implementing EPA authorities. Six years have now passed. Only one of the promised regulations has been promulgated—USDA's regulations under the Plant Pest Act. Neither the EPA regulations under the TSCA or under the Pesticide Act, nor the USDA guidelines governing agricultural research have seen the light of day.

[3] One of the promised guidelines would have implemented the USDA research authorities to establish a set of guidelines governing the release of genetically engineered animals in research. These guidelines would have covered an important set of activities involving genetically engineered animals.

The Bush Administration (working through the Council on Competitiveness in the Office of the Vice President) has gone beyond blocking implementation of the framework. It is now trying to dismantle programs—specifically the Plant Pest Act program—already in place.

The withdrawal from the arena of biotechnology policy was not instigated by the relevant Agencies. To the contrary, both the USDA and EPA, implementing the Federal Framework, have sent successive versions of proposed rules and guidelines to the White House for approval. Their efforts have been blocked by the group currently responsible for this policy-—the Council on Competitiveness .

With regard to animals, an adequate regulatory framework would require both new legislation and implementation of existing laws in ways not contemplated in the 1986 framework. Since the Council on Competitiveness will not allow even the implementation of the laws promised in the 1986 document, there is no hope for the new initiatives needed for animals.

SUMMARY

As of this NABC meeting (May, 1992), the regulation of genetically engineered animals is hopelessly inadequate, with little hope for improvement. As long as the Council on Competitiveness sets policy, existing statutes are unlikely to be implemented to regulate genetically engineered animals and no new legislation will be sought to provide the new authority needed.

From an environmental standpoint, the current situation means that the risks posed by engineered animals to the environment—whether from accidental or deliberate release—will go unassessed and uncontrolled. Moreover, without regulation there will be few opportunities for the public to know what is coming or to participate in decisions about the technology. The bottom line is that the new policy leaves it up to industry and scientists to decide what kind of animals to make and when and how they should be released. The rest of us must simply hope that their choices will not lead to environmental degradation and disaster.

This policy of secrecy and exclusion of the public is a recipe for disaster-both for the environment and for the biotechnology industry.

REFERENCES

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